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STONE CONROY

January 25, 2024

Via ECF

Honorable Michael A. Hammer, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

***Re: Teva Branded Pharmaceutical Products R&D, Inc., et al. v.
Amneal Pharmaceuticals of New York, LLC, et al.
Civil Action No. 2:23-cv-20964 (SRC-MAH)***

Dear Judge Hammer:

This firm, together with Procopio, represents Defendants (collectively, “Amneal”) in connection with above-referenced matter. We write in response to Teva’s January 24, 2024 letter regarding its forthcoming partial motion to dismiss certain of Amneal’s counterclaims and request to stay its response to *all* counterclaims until such time as that motion is decided.

There is more to Teva’s request than meets the eye. This Hatch-Waxman case was conjured into existence through Teva’s improper listing of the asserted patents in the FDA’s Orange Book. On their face, none of those patents meet the simple and clear statutory requirements for being listed there. Accordingly, Amneal filed detailed “de-listing” counterclaims seeking removal of the asserted patents from the Orange Book. (D.I. 12 at 59-76, 83-98, including Counts 1-5).

Amneal intends to move promptly under Rule 12(c) for a judgment on the pleadings and for a corresponding order that all asserted patents must be immediately de-listed from the Orange Book. That motion will be more than merely a theory of the case. *The United States Federal Trade Commission (FTC) itself has already determined that all asserted patents were improperly listed, and has demanded that Teva de-list them.* (D.I. 12 at Ex. L, attached hereto as **Exhibit 1**).

Notably, Teva’s choice to list the asserted patents in the Orange Book has caught the attention not just of the FTC, but also of several lawmakers. Senator Klobuchar recently called upon Teva to de-list the asserted patents, and Senators Sanders, Baldwin, Luján and Markey have launched a related investigation into Teva. (**Exhibits 2 & 3**, attached). These senators are

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apparently quite troubled Teva's conduct, which they view as an abuse of the Hatch-Waxman scheme that harms the public by delaying access to lower-cost generic versions of old drugs.

Unfortunately, rather than change course, Teva now seeks to double down on its harmful delay tactics. Specifically, in this litigation, rather than answer Amneal's de-listing counterclaims, Teva is moving to dismiss them. This is a delay tactic by Teva. Indeed, Amneal asked if Teva would agree that Amneal's 12(c) motion can proceed despite the pendency of Teva's motion to dismiss. Teva refused. (**Ex. 4** at 1-2). Instead, Teva contends that 1) it will not answer the de-listing counterclaims; and 2) that Amneal cannot proceed on its own motion on the pleadings, because the pleadings will not "close" until after the Court decides Teva's motion to dismiss.

As explained below, Teva's tactics and positions prejudice Amneal and harm the interested public. They also create inefficiencies that can and should be avoided by addressing both motions in tandem. Accordingly, Amneal respectfully requests that the Court deny Teva's request to forestall the progress of this case and enter an order permitting Amneal to proceed with its motion. It is well within the Court's discretion to enter such an order, and Amneal respectfully submits that the Court should exercise that discretion here, consistent with Federal Rule of Civil Procedure 1, to "secure the just, speedy, and inexpensive determination" of this case, and with Local Civil Rules 1.1, 83.2(b) and 83.3.

Prompt resolution of Amneal's motion is needed in view of the regulatory context at play. The FDA is scheduled to approve Amneal's ANDA product as early as April 30, 2024.¹ As long as the asserted patents (which the FTC has demanded Teva de-list) remain in the Orange Book, however, the FDA's approval of Amneal's product will remain merely **tentative until at least February 28, 2026**, when the 30-month stay triggered by this lawsuit is set to expire. If Amneal succeeds on its motion, however, the asserted patents will be removed from the Orange Book, the 30-month stay will dissolve, and the FDA can grant final approval of the Amneal ANDA product as early as April 30, 2024. Only then can the public begin to enjoy access to Amneal's asthma medication as a lower cost generic alternative to ProAir® HFA. Thus, a prompt ruling on Amneal's de-listing counterclaims serves the public interest and is needed to avoid substantial prejudice to Amneal.

To this end, Amneal is prepared to file its 12(c) motion by the end of February. This should give the parties enough time to fully brief and argue the motion before Amneal's scheduled FDA approval.

Accordingly, Amneal respectfully requests that the Court either (a) require Teva to file its answer to the de-listing counterclaims promptly or (b) permit Amneal's 12(c) motion to proceed even absent an answer from Teva on the de-listing counterclaims. Practically speaking, Amneal's motion will not require an answer to the de-listing counterclaims. Rather, it will be based on applying the plain meaning of the governing statutes and regulations to the literal content of publicly-available documents, as detailed in Amneal's de-listing counterclaims. Thus, even

¹ (See January 11, 2024 Letter from FDA to Amneal, attached hereto as Exhibit 5). Indeed, this represents recent two-month acceleration by FDA of its review. Its previous earliest goal date (which was in place at the time of Amneal's counterclaims) was June 25, 2024. (D.I. 12 at Counterclaim ¶121 and Exhibit X thereto).

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assuming Teva would deny all the allegations in the de-listing counterclaims, these denials would not affect the Court's consideration of Amneal's 12(c) motion, given the overwhelming credible documentary evidence and the plain requirements of the governing law.

Judicial efficiency further supports Amneal's request, as it would be far more efficient for the Court and the parties to address Teva's motion to dismiss *and* Amneal's 12(c) motion in tandem. Both motions will address the same core issue: whether the asserted patents are properly listed in the Orange Book.

Finally, regardless of how and when the parties' respective Rule 12 motions proceed, Amneal respectfully requests an order requiring discovery to proceed during the pendency of those motions. At least until the patents are de-listed, this is a Hatch-Waxman case subject to the statutory requirement that parties reasonably cooperate to expedite it. 21 U.S.C. § 355(j)(5)(b)(iii)(IV). Amneal asked Teva to agree not to seek to use the pendency of any Rule 12 motion as a basis for delaying or limiting non-antitrust-specific² discovery. Teva did not agree to this, instead stating only that it *currently* "is not attempting" to do that. Amneal should not be left to wonder whether Teva will be permitted to change its tune after filing its motion to dismiss. Nor should Teva be permitted to force the parties and the Court to extend the tight timelines of Hatch-Waxman litigation.

We thank the Court for its consideration and remain available to discuss the matter further at the Court's convenience.

Respectfully submitted,

/s/ Rebekah R. Conroy
Rebekah R. Conroy

cc via ECF: All Counsel
Encl.
RRC/btr

² Amneal is currently considering Teva's proposal to bifurcate antitrust discovery.